K111515

510(k) Summary of Safety and Effectiveness

FEB - 1 2012

Submitter:

- SPSmedical Supply Corp.
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  Rush, NY 14543 U.S.A.
  Phone: (585)-359-0130 Fax: (585)-359-0167
- Establishment FDA Registration No.: 1319130
- Date Summary was Prepared January 27th, 2012
- Gary J. Socola
  Printed name of person submitting for 510(k)

Gary J. Socola

- _____
  Signature of person submitting for 510(k)
- Vice President, Scientific Affairs
  Title of person submitting for 510(k)

Device Name and Classification

Trade Name:	SporView® Steam Self-Contained Biological Indicator
Classification Name:	Sterilization Process Biological Indicator
Common Name:	Self-Contained Biological Indicator
Device Classification:	Class II, Regulation Number 880.2800
Product Code:	FRC
Predicate Device:	SPSmedical SporView® Steam Self Contained BI (K070595)

Device Description:

The SPSmedical SporView® biological indicator consists of a self-contained unit that includes bacterial spores of *Geobacillus stearothermophilus* ATCC #7953 inoculated onto a paper filter carrier and a small glass ampoule containing Tryptic Soy Broth with Bromocresol Purple acting as a pH indicator encased in a plastic vial that serves as the culture tube.

SPSmedical Supply Corp. is using its SporView® Self Contained Steam BI (K070595) to show equivalence to the proposed SporView® self contained steam BI. Both devices are essentially the same device however; the proposed device was tested at 135°C, where as the device cleared under K070595 was tested at 121°C, 132°C and 134°C.

Intended Use:

SporView® Steam is a self-contained biological indicator inoculated with viable *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of saturated steam sterilization processes operating at 121°C and 132°C gravity displacement, 132°C flash gravity displacement and 121°C – 134°C prevacuum cycles.

SporView® self-contained biological indicators are also appropriate for use in monitoring the efficacy of saturated steam prevacuum sterilization processes operating at 135°C for 3 minutes exposure time.

Statement of Similarity to the Legally Marketed Predicate Device:

- Both devices are essentially the same device tested at different sterilization temperatures.
- Both are intended to monitor steam sterilization cycles.
- Both utilize the same strain of bacterial spores.
- Both utilize the same carrier material.
- Both use Tryptic Soy Broth as media.
- Both are activated in the same manner.
- Both are incubated at the same temperature

Non-Clinical Testing:

Testing was performed in order to validate the indicators label claims and performance characteristics. Multiple lots of indicators were tested for;

- Resistance
- Spore population
- Media recovery in extended steam sterilization cycles
- Effects of holding time
- Reduced incubation period
- Stability of the color change
- Media Evaporation
- Survival Response Time
- Effects of carrier and package materials

All test results met the defined acceptance criteria.

Conclusion:

Supportive data has demonstrated that the SPSmedical SporView® Steam Self-Contained Biological Indicator is equivalent to the legally marketed predicate device and is the same device tested at a different sterilization temperature. Therefore, the proposed device is as safe and effective as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SPSMedical Supply Corporation
C/O Mr. Gary J. Socola
Vice President, Scientific Affairs
6789 West Henrietta Road
Rush, New York 14543

FEB - 1 2012

Re: K111515
Trade/Device Name: SporView® Steam Self Contained BI
Regulation Number: 21 CFR 880.2800
Regulation Name: Biological Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: January 27, 2012
Received: January 31, 2012

Dear Mr. Socola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

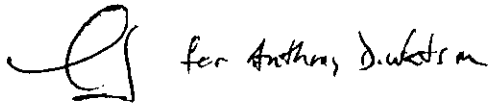
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS for USE STATEMENT

Applicant: SPSmedical Supply Corp.

510(k) Number (if known): K111515

Device Name: SporView® Steam Self Contained BI

Indications For Use:

SporView® Steam is a self-contained biological indicator inoculated with viable *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of saturated steam sterilization processes operating at 121°C and 132°C gravity displacement, 132°C flash gravity displacement and 121°C – 134°C prevacuum cycles.

SporView® self-contained biological indicators are also appropriate for use in monitoring the efficacy of saturated steam prevacuum sterilization processes operating at 135°C for 3 minutes exposure time.

Prescription Use _____ AND/OR Over-The-Counter Use __X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claxton-Wells
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111515